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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,473	10/18/2000	Brett Haarala	06530-0020	1891

22852 7590 02/21/2007  
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901 NEW YORK AVENUE, NW  
WASHINGTON, DC 20001-4413

EXAMINER
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HUH, BENJAMIN

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

09/690,473

Applicant(s)

HAARALA ET AL.

Examiner

Benjamin Huh

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 60,61,63-68,70-72,74-79 and 113-117 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-61, 63-68, 70-72, 74-79, 113-117 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 60-61, 63-68, 70-72, & 74-79 are rejected under 35 U.S.C. 102(e) as being anticipated by VILLANI (US Patent No. 5848989). Villani discloses an access port to be implanted into a patient's body including an upper body part 2, lower body part 3 attachable to the upper body part, see figure 2, a self-sealing unitary septum 4 (col. 4 lines 29-31 between the upper body part 2 and the lower body part 3, the body parts made of implantable biocompatible material (col. 4 lines 1-5), a reservoir 8 defined by the body portion and located between the septum 4 and the lower body part 3, an outlet 9, an entry site 7 located on the upper body part 2 disposed opposite the outlet 9 and configured to permit the insertion of a guidewire or stylet 13, and an access site 6 located on the body portion. The disclosed entry site shape and size and position in relation to the outlet 9 would permit the insertion of a stylet or guidewire, since stylets and guidewires vary in length, diameter, and material, through the body portion and into

the outlet, and such would be recognized by persons of ordinary skill in the art. The outer surface of the septum 4 forms a portion of an exterior surface of the device, as seen in figure 3. The prior art device also includes an access site 6 that can be seen to extend away from the reservoir substantially perpendicular to the direction extent of the outlet 9 and the entry site 7. The unitary septum 4 is comprised of first and second portions that provide access to the reservoir via the entry site 7 and the access site 6. A catheter 12 is attached to the outlet 9, see figure 3. Also wherein the device is configured to permit access to the reservoir via the access site 6 without passing through the entry site 7, see figures 2 & 3. Wherein it is noted that the application does not have any major structural limitations with respect to the access site and the access site is seen to be the area defined by the element 6 of the prior art, the access site also does not state what it necessarily gives access to. It is also noted that the amendment of "wherein the device is configured to permit access to the reservoir via the access site without passing through the entry site" is a negative limitation and it is suggested by the examiner to amend to utilize a positive limitation. For example, access site 6 is seen to be the open space in a hallway down the corridor walls which are comprised of element 2, and the walls of element 3 are seen to be bookshelves lining the halls, therefore even though there is another element in the hallway the middle section is still deemed a hallway, therefore the middle section of element 6 is still deemed to be an access site, also see the attached figure 3 with further clarification of the access site.



discloses an access port in figures 2-4 comprising a body portion comprising an upper and lower body part, a self-sealing septum 56, a reservoir (seen as elements 52, 20, & 54) defined by the body portion, an outlet 42 configured to be in flow communication with the reservoir, an access site (seen as the opening above septum 56) located on the body portion, an entry site 14 disposed opposite the outlet and being configured to permit insertion of one of a guidewire and a stylet 66, one of a guidewire and a stylet 66, and wherein the device is fully capable of permitting access to the reservoir via the access site without passing through the entry site, also see col. 5 lines 39-56.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 113-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over VILLANI (US Patent No. 5848989) in view of Kirsch et al (US Patent No. 5385541). Now even though Villani does not explicitly disclose the use of a guidewire or stylet, attention is directed to Kirsch. The Kirsch reference teaches in figures 7 & 8, the use of a guidewire in an access port. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to incorporate the guidewire 60 of Kirsch into the device of Villani in order to help guide needle 13 of Villani to the desired location.

### ***Response to Arguments***

Applicant's arguments filed 11/15/06 have been fully considered but they are not persuasive.

Applicant argues that Villani does not disclose an access site, the examiner disagrees. The device of Villani discloses an access site 6 which can be permit access to the reservoir via the access site without passing through the entry site, see the rejection above with newly added figure and explanation for clarification purposes. Wherein since the access site 6 is already next to the reservoir there is no need to pass through the outlet or entry site.

### ***Conclusion***

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

